REMARKS

Status of Claims

Claims 1 – 64 were original in the application. Claims 2, 11, 40, and 62 - 64 have been cancelled without prejudice. Claims 7, 8, 17, 19, 20, 23, 26, 27, 31, 34 – 36, 44 – 46, 48 – 50, 52 – 54 and 58 – 61 have been withdrawn. Claims 1, 7, 9, 12, 16, 18, 19, 23 – 26, 29, 33, 37, 38, 44, 48, 50, 53, 55, 59, and 60 have been currently amended. Claims 1, 3 – 6, 9, 10, 12- 18, 21, 22, 24, 25, 28 – 30, 32, 37 - 39, 41 – 43, 47, 51, and 55 – 57 as amended are submitted as being set forth in a clearly allowable condition or at least is a better form for appeal.

***Claim Rejections* - 35 *USC* § 112**

All instances of the words, "Integra" and "FortaPerm" in the specification appear in capitalized form and in close proximity to a generic description for the same. No specific location was identified where this was lacking.

In claim 1 the skeleton of the pouch is formed by the piezoelectric pumps, which as the Examiner notes is substantially less biodegradable than the pouch. Small amounts of silicon can in fact be absorbed slowly by the body, but as the Examiner correctly notes the pouch will degrade first and the device cease to function. However, this does not occur until the medical function of the device has first been completely served, namely the medicating agents dispensed in a control and local manner.

In claim 1 the use of the word "proximate" is correct. The Examiner is confusing "proximate" with "proximal", the latter being referenced to frame of reference, but the

former being only a relative relationship between two bodies. "Proximate" is defined in Merriam-Webster as "very near". No point of origin is required to establish meaning of one object being very near another.

Claim 11 has been cancelled.

Claim 25 has been responsively amended.

Claims 7, 9, 12, 16, 18, 19, 23, 26, 29, 37, 38, 44, 48, 50, 53, 55, 59, and 60 have been responsively amended. Claims 7, 23, 26, 44, 48, 50, 53, 59 and 60 were withdrawn, but objection was nevertheless made by the Examiner. The withdrawn claims were responsively amended, assuming this to be possible.

Claim Rejections· 35 USC § 102

Claims 1, 3, 5, 6, 12-16, 18, 22, 24, 25, 28, 29, 32, 33, 37, 38, 39, 41, 42, 43, 47, 48, and 55 were rejected as being anticipated by Soykan et al US Patent 6206914.

The Examiner contended that Soykan discloses an implantable apparatus comprising: an implantable pouch (col 3, lns 6-31; col 8, lns 63-67; col 9, lns 38-60; col 10, lns 4-8; col 12, lns 51- 65; col 13, lns 16-28; col 14, lns 26-39; col 15, lns 5-12; col 16, lns 23-27, lns 42-61) having multiple chambers composed of a bioabsorbable material and multiple medicating agents disposed in said chambers (col 4, lns 18-32; col 8, lns 56-67, col 9, lns 35-37; col 9, lns 38-59, col 12, lns 51-65; wherein each of the microscopic containment vehicles forms a chamber and each of the containment vehicles is capable of containing various cells and therapeutic agents); multiple implantable piezoelectric pumps (col 4, lns 18-32; col 12, lns 51-65; col 13, lns 16-27; col 14, lns 26-39) fabricated in the pouch which forms a skeleton of the pumps, the

pumps being configured to transfer medicating agents to said patient (col 4, Ins 18-32; col 12, Ins 51- 65; col 13, Ins 16-27; col 14, Ins 26-39); and an implantable, biocompatible and bioabsorbable skin (col 9, Ins 38-60, col 10, Ins 4-col 11, Ins 14) covering the pouch and pumps; and an implanted control circuit (col 4, Ins 18-32, col 13, Ins 16-27, col 14, Ins 10-39, col 15, Ins 4-24, col 16, Ins 18-61) to control proper dosing and scheduling of said medicating agent in a closed loop control mode so that control of the operation of the system is performed autonomously as determined by locally sensed homeostatic parameters (col 3, Ins 6-31; col 8, Ins 63-67; col 9, Ins 38-60; col 10, Ins 4-8; col 12, Ins 51-65; col 13, Ins 16-28; col 14, Ins 26-39; col 15, Ins 5-12; col 16, Ins 23-27, Ins 42-61; and as further set out in the discussion in Response to Arguments).

Soykan is clearly directed to a localized delivery of an implantable stent and not an implantable pouch with multiple chambers composed of a bioabsorbable material as required by claim 1. See col. 1, line 56; col. 2, lines 10, 30, 30 - 40, and 57; col. 3, lines 7, 10, and 17; col. 8 line 58; col. 9, line 40. As stated at col. 1, lines 10 -20, Soykan's device is an implantable system such as a stent, vascular graft, or stent graft that serves as a carrier for genetically engineered endothelial cells, which are capable of producing and releasing a therapeutic agent for on-demand localized treatment of conditions such as coronary artery disease. The cells release the therapeutic agent upon the application of an electrical stimulus. There is no implantable pouch or anything that resembles an implantable pouch with multiple chambers and multiple medicating agents contained in them.

Note should be taken of how the Applicant forms the biodegradable pouch. As noted in Figs. 6J, 6K, and 6M, two different pouch formations are illustrated. Soykan uses a stent formed out of metal or polymeric material which is subsequently coated by biodegradable elements and cells, while Applicant uses a collagen skeleton with a specific dura to form the bio-degradable skeleton of the pouch. Claims 38, 63 and 64 have been rewritten into claim 1 as amended. The disclosed scaffolding and the pouch synthetic bio-degradable cover (manufactured by Integra) substantially departs from the Soykan approach which limited to only those means which can be delivered with a stent.

Consider the references made to Soykan which are alleged as disclosing an implantable pouch with multiple chambers composed of a bioabsorbable material:

- Col 3, Ins 6-31, call for an "intraluminal stent".
- Col 8, Ins 63-67, call for a "carrier (e.g. stent)".
- Col 9, Ins 38-60, call for "stent" made of or coated with a polymer film.
- col 10, Ins 4-8, call for a coated "stent".
- col 12, Ins 51- 65, call for a "microscopic containment vehicle" which is disclosed as micromachined structures or microactuators such as hinged rigid plates on a silicon substrate forming a cube to contain the cells. Col. 12, line 66 – col. 13, line 15.
- col 13, Ins 16-28, call for a "microscopic containment vehicle" including polymeric pumps, reservoirs and valves. The cells are to be included in the reservoir.

- col 14, lns 26-39, call for a "carrier" having a surface on the which the cells are located.
- col 15, lns 5-12, call for the electronics to be included in a sealed enclosure. There are no medicating agents in the sealed enclosure.
- col 16, lns 23-27, lns 42-61, call for a "sensing element" or "sensors". There is no disclosure relevant to an implantable pouch with multiple chambers composed of a bioabsorbable material containing medicating agents.

Consider the contention of the Examiner that Soykan discloses an implantable, biocompatible and bioabsorbable skin covering the pouch and pumps.

- col 9, lns 38-60, call for the cells to be incorporated into a polymer film or coating on the stent. A coating or film on a stent is not a skin enclosing a scaffolding to form a pouch for containing a medicating agent.
- col 10, lns 4-col 11, lns 14, call for the stent to be coated with fibrin or encased in a sleeve of fibrin film. Again a perform for a stent is not a skin enclosing a scaffolding to form a pouch for containing a medicating agent. The sleeve or perform described in the references Muller and Dinh is in the form of a coating or film and is not in the form of a pouch-forming skin.

Consider scaffolding which provides a skeleton for the pouch and which is comprised of collagen forming a matrix capable of degrading over time. The Examiner contends that Soykan shows a scaffolding fabricated in the pouch which forms a skeleton of the pumps:

- col 4, lns 18-32, call for a delivery device comprising a carrier (e.g., stents, vascular grafts, stent grafts) and eukaryotic cells, which can optionally be enclosed within containment vehicles. There is no collagen scaffolding on which a skin is disposed to form a pouch.
- col 12, lns 51- 65, call for a microscopic containment vehicle coated onto the stent. Again, there is no collagen scaffolding on which a skin is disposed to form a pouch.
- col 13, lns 16-27, call for the microscopic containment vehicle to include polymeric micropumps, reservoirs and valves. No disclosure of collagen scaffolding on which a skin is disposed to form a pouch is provided. No enabled structure is disclosed for the reservoir.
- col 14, lns 26-39, call for mechanically stressing the cellular membranes and has no relevance to a collagen scaffolding on which a skin is disposed to form a pouch.

The disclosure of a multiple chambered pouch containing multiple medicating agents is missing as required by claim 1 and there is no disclosure of a collagen skeleton with a specific dura to form the bio-degradable skeleton of the pouch in Soykan as required by claim 1 as amended. Hence, each and every element of claim 1 as amended is not disclosed by Soykan and a holding of anticipation by Soykan not sustainable.

Claim 1 is also distinguished from Soykan by the failure of Soykan to disclose the local control. A practitioner with ordinary skill in the art viewing Soykan's Figs. 1, 2-1, 2-2, 3, 4, must seriously question whether or not local delivery and local control of medicating agents is disclosed in Soykan, especially given the amount of electronics

shown in Fig. 5 which cannot be physically located within a stent. Soykan must not only disclose the claimed element against which it is cited, but must also provide an enabling disclosure. The Examiner contends that Soykan's local control is embedded within the stent, which is a conclusion which assumes operability without any supporting disclosure.

Claim 1 calls for an implanted control circuit proximate to the implanted pumps to control proper dosing and scheduling of the medicating agents in a closed loop control mode so that control of the operation is performed autonomously as determined by locally sensed homeostatic parameters.

The Examiner relies on the following portions in Soykan to show an enabled disclosure of an implanted control circuit as claimed:

- col 4, lns 18-32, call for a delivery device comprising a carrier (e.g., stents, vascular grafts, stent grafts) and eukaryotic cells, which can optionally be enclosed within containment vehicles. There is no reference to any circuitry in this portion.
- col 13, lns 16-27, call for piezoelectric pumps in the containment vehicle, but again there is no reference to any implanted circuitry.
- col 14, lns 10-39, call for a stimulation device to provide electrical stimulation, mechanical stimulation, acoustic stimulation, thermal stimulation, chemical stimulation, or combinations thereof, to the eukaryotic cells and/or the containment vehicles. Col. 5, lines 4 – 6 makes it clear that the stimulation device 22 shown in Fig. 2-1 is not implanted, but remote from the delivery device.

- col 15, lns 4-24, call for remote stimulation device 22 in Fig. 2-1 with the circuitry of Fig. 5. Clearly, the control circuit is not implanted.
- col 16, lns 18-61, call for remote stimulation device 22 in Fig. 2-1 with various modifications, none of which cause it to be implanted with the delivery device.

The Examiner further cited the following portions of Soykan in the Response to Arguments to show an implanted control circuit:

- col 3, lns 12-30, call for an implanted delivery device and stimulating device, but do not disclose an implanted control circuit. In fact, control of the stimulating device is never mentioned in this portion of Soykan.
- col 13, lns 16-27, 47, call for containment vehicles with pumps, valves and reservoirs and an implantable stimulating device, but again control of the stimulating device is never mentioned in this portion of Soykan.
- col 14, lns 58, call for a wide variety of stimulating devices, but once again control of the stimulating device is never mentioned in this portion of Soykan.
- col 15, lns 5-12, calls for an implantable stimulating device, but control of the stimulating device is disclosed as linked by telemetry to a remote control circuit which is not implantable.
- col 17, lns 15-20, call for an inductive RF driver circuit to be implanted in the stent, which driver is controlled by a remote source of RF energy controlled to actually determine the dosages dispensed. The inductive RF driver circuit merely generates a DC signal from received RF controlled by

a remote control circuit. The driver circuit is not a control circuit for dosing and scheduling the scheduling of the medicating agents in a closed loop control mode.

The Examiner contends that the "control circuitry" for electrically stimulating the piezoelectric pump to stimulate release of the therapeutic agents from the multiple microscopic containment vehicles is located on the stent itself. This is incorrect. The RF driver circuit for generating a DC voltage for electrically stimulating the piezoelectric pump to in turn stimulate release of the therapeutic agents from the multiple microscopic containment vehicles is located on the stent. That RF driver circuit is controlled by a remote control circuit that selectively generates the RF to which the driver is exposed. The RF driver is totally passive and controls nothing. It has no control functions in and of itself.

The contention of the Examiner might be analogized to stating that "a TV receiver as being a controlled source of television signals itself", which is false. The television transmitter is the remote television control device and the television signal displayed by TV receiver, if any, is controlled by the remote television transmitter, which is not in the TV receiver itself.

Soykan fails to disclose a control circuit implanted with the delivery device. Hence, each and every element of claim 1 is again not disclosed by Soykan and therefore not anticipated by the reference.

Claims 3, 5, 6, 11 - 16, 18, 22 , 24, 25, 28, 29, 32, 33, 37, 38, 39, 41, 42, 43, 47, 48, and 55 depend directly or indirectly on claim 1 and are allowable therewith and for such further limitations as contained therein.

Claim Rejections* - 35 *USC* § *103

Claims 4, 9, 10, 21, 30, 56, and 57 were rejected as being obvious over Soykan in view of Humes et al US Patent Publication 2002/0090388).

Claims 4, 9, 10, 21, 30, 56, and 57 depend directly or indirectly on claim 1 and are allowable therewith and for such further limitations as set forth therein.

Applicant respectfully requests advancement of the claims to allowance.

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